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FOOD ADDITIVE CONTROL

IN THE U.S.S.R.



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FOOD ADDITIVE CONTROL IN THE U.S.S.R.

by

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INTRODUCTION

In the U.S.S.R., no substance proposed as a food additive may be utilized in food production until it has been officially approved by the Medical-Epidemiological Service of the Ministry of Health. This regulation, established more than 40 years ago, is still strictly adhered to at present. Such precaution is essential, because the addition of substances to food products can only be considered safe once such substances have been proved harmless.

There is, moreover, a strong tendency in the country to limit the use of additives in food production, essentially because it is believed that the various chemical food additives are, in fact, alien to the human body and have no nutritive value. And, no matter how much may be known on the subject, it is difficult to ensure their absolute safety. Consequently, it is more reasonable to limit the introduction of food additives than to permit their general use.

The results of research on proposed food additives is screened in the U.S.S.R. by select scientific committees which submit their recommendations, based on this evidence, to the Ministry of Health. The ministry's decision is binding on industry. Application is controlled by local public health authorities (the medical-epidemiological stations) staffed by specialists in food hygiene. As mentioned earlier, this procedure has been in existence in the U.S.S.R. for several decades; its implementation is undoubtedly greatly facilitated in a country with a planned economy and a nationalized industry.

In conclusion, it should be pointed out that the present report is far from exhaustive. There are so many food additives at the present time that, with the best of intentions, it is well-nigh impossible to cover in full the characteristics of each one of them. This monograph represents an attempt to set out:

(a) the theoretical considerations which, in the U.S.S.R., guide the approach toward a solution of this complex and, from the standpoint of health, important problem;

- (b) the present situation in the country; and
- (c) the practical health measures being taken to regulate the use of foreign substances in foods.

A guiding rule in the use of additives should be that no substance shall be added to foods until its toxicity and, in some cases, its possible carcinogenic properties have been investigated. The use of a new food additive must not be permitted until there is certainty that its presence in the diet is safe even under conditions of prolonged daily or continuous absorption.

1. BASIC PRINCIPLES GOVERNING THE USE OF FOOD ADDITIVES

In the past few years there has been a sharp rise in the use of chemical substances and natural compounds to prevent the spoilage of foods and beverages or to improve their characteristics and keeping qualities. These substances, which have no nutritive value, are termed food additives and include a variety of substances introduced into foods to improve their appearance, taste, aroma or consistency (colouring matters, flavouring agents, emulsifiers, etc.) and their keeping qualities (antioxidants, preservatives, antibiotics, etc.). They consist of thickeners, bleaching agents, neutralizers, stabilizers, bacterial and fungal enzyme preparations, etc., used for various other technological purposes. A serious public health problem has arisen in many countries as the use of food additives becomes more widespread. In addition, progress in chemistry has made it possible to produce various synthetic substances which are being used extensively in the food industry and in agriculture: plastic packaging materials and foil wrappings, elastic materials from synthetic and natural rubber, varnishes, coatings, cleansing agents and disinfectants, pesticides, growth regulators, fertilizers.

A certain residue of the pesticides used in agriculture that are resistant to environmental factors and to heat treatment remains on crops and in the foods produced from these crops. Impurities may also enter foodstuffs through contact with various implements, containers, packaging materials, etc., during treatment, processing and storage. There are also the substances which may form in foodstuffs as a result of particular production methods and of such treatment as smoking, ultraviolet and ionizing irradiation, the application of ultrasonic vibration, and also as the result of the use of hormonal preparations for fattening young farm animals and poultry. Moreover, there is a constant increase in the manufacture of synthetic nutrients such as vitamins, fatty acids, protein and other hydrolisates, and of new products based on raw petroleum,

natural gas, and so on. The prolonged absorption of these substances may certainly affect health. The possibility in these circumstances of acute or chronic poisoning, or of a mutagenic, carcinogenic or similar effect is not to be excluded.

The deleterious effects of different chemicals contained in individual foodstuffs or in the entire dietary intake may vary considerably in nature and intensity. Admittedly, the problems arising from acute food poisoning are relatively simple from a medical standpoint, since in acute poisoning the subject becomes ill immediately or at least within a relatively short time. The accompanying clinical picture in such cases is always rather well defined, presenting a pattern of symptoms characteristic of poisoning by a given substance. Acute poisoning is immediately recognizable and, as a result, the cause can be determined and measures taken to prevent its recurrence.

Chronic poisoning presents considerably greater health hazards than acute intoxication because its symptoms are frequently vague and because they appear only very gradually, as the body absorbs regularly repeated, even though relatively small, amounts of the foreign substance over prolonged periods, sometimes even for decades. Yet, since their danger is not recognized, such substances are widely used in food production.

The problem of intentional and unintentional food additives presents difficulties because it involves the absorption of small amounts of substances over very long periods, at times exceeding the life span of a generation. It also involves the possibility of mutagenic and carcinogenic properties, mentioned previously, of allergenic properties and indirect toxicity caused not so much by the noxious qualities directly but by the sum total of the changes produced in a food as a result of the foreign substances added to it. The problem of food additives becomes even more complex when one realizes that, in practice, the "pure," distinct effect of any single substance is rarely if ever seen; one is usually faced with the manifestations of an entire group of chemicals.

Among the causative factors contributing to the development of chronic poisoning is the property of many chemical substances to accumulate. Therefore, the direct result is a cumulative effect and the indirect result a toxic one. Cumulative properties are exhibited by many substances which enter into foodstuffs. And, while some of them, such as most trace elements, exhibit only a tendency to accumulate, and others, such as the carcinogenic colouring matters, only the ability to produce an added effect, there are a number of substances which disclose both material

and dynamic cumulative properties, e.g., radioisotopes, organic chlorinated pesticides, etc. Thus, although no toxic effect may be noticed after the ingestion of a single small dose, or even of several small doses taken over a brief period, prolonged use of the substance may cause its accumulation in the body (material cumulation) or a reinforcement of its action (accrued effect). This process involves a complex interrelationship between the biological activity of the substance, the dosage, the rate at which the substance is eliminated from the body, the time interval between each ingestion, and the threshold at which the body begins to show signs of chronic toxicity. In this process, what is of considerable importance are the properties of a substance which determine its retention in the body; these may be either physical or chemical. Foremost among the physical characteristics contributing to the development of chronic toxicity is the ready solubility of a substance in fat, with accompanying poor solubility in water, which impedes its elimination from the body.

Apart from physical factors, cumulation is also produced by a chronic affinity, as exemplified by fluoride compounds. These substances are used widely in agriculture and are found in considerable quantities in natural spring water and in foodstuffs. Their prolonged intake may produce a chronic condition (fluorosis), due to the property inherent in fluorine to replace phosphate, particularly in bone tissue. This affinity is also manifested by some radioisotopes, heavy metals, etc.

An example of cumulation of additive action is the colouring matter naphthol yellow s, which had been used as a food colour in many countries prior to 1961, but which was found to have carcinogenic properties. The rapid development and the number of hepatomas in rats may be attributed not only to the size of the dose and to the duration of the activity of this colouring matter but also to its repeated administration which results in reinforcing its effect. Frequent small doses of this substance proved to be more deleterious than large ones administered rather infrequently.

Cumulative effect is exhibited by many substances in foods, among others by antibiotics. In this connection, the question of extremely low doses poses a serious problem. Modern toxicology bases its concept of tolerated concentrations on the assumption that, if a given substance administered to test animals for a period of time, rarely exceeding one year, produces no ill effects, such substance, appropriately corrected for safety (i.e., by decreasing the dose tolerated by test animals 50 to 200 times), may certainly be introduced into human nutrition or into the feed of meat- and

milk-producing animals. However, toxicological and health considerations on which this safety factor is based are still, in most instances, not scientifically justified. There is no assurance that a substance found to be safe in amounts tolerated by the body (sometimes very high concentrations) will not prove harmful in very small amounts when repeated over prolonged periods, and that its cumulative action might not produce damage owing to the failure of the body's protective-adaptive mechanism to counteract it. For the most part, this aspect of the problem has not yet been clarified.

Extremely low doses are directly associated with the carcinogenic and mutagenic properties of substances. Although foodstuffs contain numerous foreign substances, in the overwhelming majority of cases it has still not been ascertained whether, for man, they represent a risk of cancer or mutation. Investigations in this field are being carried out in many countries, and with increasing frequency substances which had been considered harmless and had been in use for a long time are now reported to be carcinogenic or mutagenic. Every year new substances are added to this list, which already includes elements of the polycyclic hydrocarbon group of tobacco or wood smoke, some food colours (naphthol yellows and other azo colours), polymer compounds (wax, tars, paraffin, etc.), pesticides (aramite), steroid hormones, radioisotopes, etc.

Assessment of the carcinogenic hazards of substances which are added to foods warrants very special attention, since the presence of carcinogens in the diet may be an important factor contributing to cancer in man. Therefore, food additives and food processing methods should be adequately investigated in order to eliminate to the maximum extent possible any hazard to health. Unfortunately, there is at present a considerable shortage of scientific information concerning not only the toxicity but also the possible carcinogenic properties of many food additives. However, it has been conclusively established that the continuous action of carcinogenic substances causes the appearance of tumours sometimes months and even years after the administration of the carcinogen has been interrupted. There is no direct correlation between the amount of the carcinogen ingested and the appearance of tumours; in some especially susceptible persons even insignificant amounts may provoke tumours. This is due to the fact that carcinogenesis depends on a multiplicity of factors of such complexity that no absolutely safe level can as yet be established for carcinogenic substances in the diet.

The so-called cocarcinogenic agents, which reinforce the effect of

carcinogens under appropriate conditions, also represent a definite hazard. Such agents have been discovered among the emulsifiers permitted in certain countries (Spans, Tweens, and others), esters of fatty acids, detergents (surface-active agents, silicon-organic compounds), etc.

The extent to which the carcinogenic and mutagenic properties of a given substance are related is not yet known, although both processes directly affect cell mitosis. In any event, it may be assumed that a carcinogenic substance may be free from mutagenic properties, and vice versa. Thus, formaldehyde is a strong mutagenic agent but has not been found to possess carcinogenic properties. The problem of mutagenicity, like that of carcinogenicity, is of increasing concern in view of its relation to the growing incidence of abnormalities at birth. As a result, the deleterious effect on heredity of substances entering the human body is the subject of intensive investigation in many countries. On the basis of the data available, it can be assumed that most foreign substances enter the body through food and drinking water. At the present time, those considered to have the most pronounced mutagenic effects are phenols, heavy metals, arsenic, almost all alcohols, the by-products of protein decomposition, antibiotics, purines, peroxides, lactones, etc.

In addition to their direct toxic action, foreign substances in foods may also cause adverse effects indirectly, notably as a result of decomposition (e.g., of vitamins, protein, etc.), of interaction with food compounds (e.g., as in the case of sulphur dioxide), the transformation of nutrients into toxic products (nitrogen trichloride), the impairment of digestion (antitrypsin factors in soybean flour, etc.), reduced absorption, etc. This, in turn, may cause qualitative nutritional deficiencies or chronic poisoning. The indirect noxious effect of foreign ingredients in foods may take the form of changes in the intestinal flora, as the use of antibiotics both in food and in animal feed well exemplifies. Unfortunately, it must be noted that this aspect of the toxicity of foreign substances has not yet been fully clarified. Similarly, there are practically no studies concerning the possible allergenic effect of such substances, although the literature contains frequent mention of this disorder.

Modern advances in enzymology have added much new information to explain the mechanism of the toxicity of foreign ingredients in food-stuffs, but such information is decidedly incomplete: there are almost no studies concerning the effect of these substances on the hormonal regulation of metabolism; there are not enough investigations of the combined, or otherwise joint action of the various extraneous substances, most

of which are contained in the diet. All this points to the fact that the extremely intricate and complex problem of food additives, far from having become less pertinent has, on the contrary, become more acute from the standpoint of public health. Since the proper solution of the problem posed by the addition of foreign substances to foods is of paramount importance to health, it is being dealt with by a number of international organizations, among them FAO, WHO, their respective committees of experts, the European Committee for the Protection of the Population against the Hazards of Chronic Toxicity (EUROTOX), and others.

Owing to the special features of Soviet public health legislation, etc., the problem of food additives in the U.S.S.R. is not as critical as it is in a number of other countries. Nevertheless, the production of various chemicals, such as preservatives, antioxidants, etc., has also increased in recent times.

In the U.S.S.R., the addition of substances to foods is regulated by public health provisions and by technical instructions and directives issued by the Main Medical-Epidemiological Division of the Ministry of Health. And, as regards food additives, the principle followed is "that which is not authorized is forbidden." Where public health is concerned, this appears to be the soundest attitude.

Substances which have not received the approval of the public health authorities are illegal for use in food production. Permitted food additives must conform strictly to governmental food standards, technical specifications, or special technological directives. Contaminants which may enter foods during treatment or processing are also controlled. Before any chemical substance is permitted for use as a food additive, it is subject to research and investigation to determine its possible toxicity and, if necessary, its carcinogenicity, in order to safeguard the consumer against health hazards arising from its addition to foods. These investigations are carried out in the research institutes of the Soviet Ministry of Health and of the Academy of Medical Sciences, as well as by the general hygiene and food hygiene departments of state medical institutes and institutes for advanced medical studies.

Both in theory and in practice, Soviet authorities always have recommended that additives be kept to a minimum in the production of foods. For this reason, the number of permitted chemical substances, no matter what their purpose, has always been and still is much smaller in the U.S.S.R. than in North America and most west European countries. Thus, for instance, Canada allows the food industry to use 15 synthetic colouring

matters, the Federal Republic of Germany 19, while in the U.S.S.R. only 3 synthetic colours are permitted; the situation is analogous in respect of other food additives. Some countries - Belgium, Denmark, Ireland and Pakistan, for instance - have no list of permitted colouring matters at all. However, the subject is considered of extreme importance in the U.S.S.R. and various branches of the food industry (canning, vegetable and fruit drying, confectionery, etc.) are constantly conducting experiments in their laboratories and institutes to find new, more effective, more easily obtainable and more economical chemical substances to use as food additives. Every concrete proposal for the introduction of a new additive presented by a trade research institute must be approved by the public health bodies; should there be the slightest possibility of its adverse effect on health, special experimental research is required. The replacement of one chemical substance by another is sometimes made necessary not for reasons of technical or economic advantage alone, but due to new scientific evidence indicating the unequivocal toxicity of a substance. The basic criterion for a new food additive is the safety aspect both of the additive itself and of the foodstuffs treated with that substance. Authorization to use a food additive is denied in the U.S.S.R. if the intended effect can be obtained by a technically and economically suitable technological process. Further, additives are also prohibited if their presence is likely to conceal technological deficiencies, spoilage, or to lower the nutritive value of a food. Hand in hand with control over the introduction of new food additives, it is vitally important to subject additives already permitted to continuing observation. These must be subjected to reexamination and more thorough investigation as new knowledge comes to light and as research methods are perfected.

2. CONTROL METHODS

The basis of Soviet legislation governing food quality is the food standard. A standard is a document which sets out optimum food characteristics based on the quality criteria of a typical model specimen. Standards in the U.S.S.R. are enforced by law and are approved by the Council of Ministers' Committee for Standards, Measures and Measuring Instruments. These standards, known as the All-Union Governmental Standards (GOSTS), must be observed by all institutions in the country; those issued by the individual republics are indicated by the letters RST. Where there are insufficient grounds for the establishment of a GOST, the practice is to work out technical specifications (TUS) jointly for a number of republics, within a republic itself, or provisional specifications, which are binding on industry to the same degree as those of a GOST. These documents also indicate the basic norms and characteristics to which foods must conform.

A proposed governmental standard for a new food additive is approved only where the Medical-Epidemiological Service of the Ministry of Health confers a favourable opinion. Tus issued by an individual republic and having legal status in the territory of that republic are brought into line with the Gost in cooperation with the individual Ministry of Health. The aim of the public health officials in elaborating and approving food standards is to ensure that sound decisions are taken with regard to food characteristics and properties which have a bearing on the health of the consumer. A Gost prescribes the quality for the primary foodstuff from which a food is produced and specifies the properties of the additives which are used in the production of that food. Certain data are given concerning its chemical composition (the proportion of dry matter, moisture, fat content, sugar content, etc.) and provision is made to limit the degree of some impurities (heavy metals, trace elements, etc.).

On approval, a GOST is assigned an official title and number, like any other technical document; in it the food product to which the standard applies is defined and classified as to class, group and brand, in accordance with its basic characteristics. The section on technical criteria sets out the conditions which the standardized food product must fulfil in respect of appearance, form, organoleptic and physicochemical characteristics. Whenever appropriate, biological data are also included in this section.

The method of sampling and other directions regarding the procedure to be followed in testing the product from a given batch, as well as the conditions to be observed in taking a food sample, are set out in the section on sampling regulations. The correct packaging, marking and certification of a food product, as well as the proper conditions for its storage and transport are also specified in appropriate sections. And, among other provisions concerning food, a GOST covers those which have a bearing on health. The quality of food products and their conformity with the specifications prescribed are controlled by standard procedures. A GOST stipulates the particular testing procedures which are mandatory for a given food. The procedure is described either in the GOST itself, or in special GOSTS, issued under the title Testing methods. For almost every product put out by the food industry there are standardized analytical procedures prescribed both for arbitration purposes and for day-to-day food inspection. This gives legal weight to dependable testing methods especially suited for the appraisal of foods.

The GOST for any given food product indicates the methods to be used for the assay of a particular additive, e.g., preservative, antioxidant, improving agent, etc. The verification that the quality of a food is in accordance with the standards prescribed in GOSTS and TUS is carried out in the laboratories of the industrial enterprises producing the particular food product concerned.

The conformity of foods with the standards for health and hygiene is verified through random analysis by the Medical-Epidemiological Stations (SES) of the Ministry of Health. Such stations exist at the republic, municipal and local levels, and the scope of the laboratory investigations under the food hygiene control programme varies in accordance with the category of the particular SES. The sanitary control of foodstuffs by SES is done both for routine food hygiene inspection, and also whenever special evidence warrants it. The food samples for this control are procured in accordance with the Regulations for the procurement of samples of foods, beverages, and spices for laboratory investigation, approved by the Ministry of Health of the U.S.S.R. The purpose of taking food samples for sanitary investigation is to check whether the original foodstuff and the finished food product fulfil the specifications of GOSTS and TUS and meet other established conditions; or to analyse a food when special evidence indicates that it may be spoiled, contaminated, or may contain impurities, etc.

In taking a food sample for analysis, the health inspector is guided by the existing GOST or TU applicable to that food product; these documents specify both the amount of product required for an analysis and the procedure which he must follow in selecting the sample. He also relies on the regulations approved by the chief national health inspector of the U.S.S.R. The extent of the investigative work required is determined by the SES physician.

SES tests the food product for wholesomeness (signs of spoilage) and for compliance with the sanitary standards prescribed in GOSTS and TUS (presence of additives, impurities, toxic chemical residues, etc.). Depending on the evidence obtained, SES public health specialists decide whether the consumption of the analysed food product shall be permitted, determine whether it complies with the GOST, and prescribe conditions under which it may be marketed.

Whenever a new method for preservation, colouring, or other technological food process is elaborated by the food industry, calling for the introduction of an additive, preservative, colouring substance, etc., for which no authorization has yet been issued by the health inspection bodies, the food industry concerned submits the case for decision to the Ministry of Health. The ministry makes a decision on the basis of the conclusions arrived at by the research institutes and, if necessary, orders toxicological analysis and an evaluation of the carcinogenic risks from the newly proposed additives. The results of the investigations make it possible to determine whether the substance shall be permitted in food production and, if need be, its maximum permissible concentration in foods. The method proposed by industry for the identification of the substance in food is also verified. The testing method for the detection and identification of a substance in food must be sufficiently specific, sensitive and simple in order to be of use in ses laboratories and in any other testing laboratory.

The toxicological investigations and testing for carcinogenicity are performed by the customary classical methods. The techniques are consistent with those recommended by the Joint FAO/WHO Expert Committee on Food Additives, second report, and fifth report.

¹ FAO. Procedures for the testing of intentional food additives to establish their safety for use, Geneva, 17-24 June 1957. Rome, 1958. FAO Nutrition Meetings Report Series No. 17.

² FAO. Evaluation of the carcinogenic hazards of food additives, Geneva, 12-19 December 1960. Rome, 1961. FAO Nutrition Meetings Report Series No. 29.

3. REGULATIONS ON FOOD ADDITIVES

From the point of view of their technological uses, food additives may be divided into the following groups:

- I. Colouring matters. Substances used to colour foods.
- II. Preservatives. Substances used to prevent spoilage caused by bacterial activity, fungus and mould, and to prolong the keeping quality of foods.
- III. Antioxidants. Substances used to inhibit the oxidation of fats during storage.
- IV. Acids and bases. Substances used to impart a certain tartness to foods or to alter the acidity of the medium (i.e., to lower the pH in canned products or to prevent the crystallization of jams and jellies). Some bases become ingredients of baking powders used in pastry production and of powders for effervescent beverages.
- V. Flavouring agents and taste enhancers. Aromatic substances, both natural and synthetic, used as components of food flavours or directly in foods; and artificial sweeteners.
- VI. Gelling agents, stabilizers and emulsifiers. Substances used to produce or maintain a certain consistency in foods.
- VII. Improving agents. This group includes chemical compounds which enhance one or more of the quality criteria of foods (flavour, consistency), and substances used for polishing and glazing confectionery products.

Colouring matters

The colouring of foods is regulated in the Soviet Union by the Sanitary regulations for the colouring of foods, flavouring substances and beverages, approved by the Ministry of Health in 1950. Both natural and synthetic colours are permitted for use in foods.

TABLE 1. - COLOURING MATTERS Organic, synthetic and inorganic

Substance	Synonym	Chemical group and colour index number	Empirical formula	Chemical name	Colour in water or oil solutions	Permitted in:
Amaranth	Acid bordeaux B Monoazo Naphthol red s FD and c red No. 21	Monoazo *16185	C20H11N2O10S3Na3 Azo-beta-naphthol		Fuchsia red	Confectionery, al- coholic and non- alcoholic beverages
Indigo-carmine	Saxon blue FD and C Blue No. 2	Indigo 73015	C ₁₆ H ₈ N ₂ O ₆ S ₂ N ₃	Sodium salt of indigo Blue disulphonic acid	Blue	Confectionery, pastry creams
Tartrazine	Acid yellow FD and C Yellow No. 5	Pyrazole 19140	C16HeN4OoS2Nas	Trisodium salt of hydroxyl-5-p sulphophenyl-1-p sulphonphenylazo-4 pryazole-3-carboxylic	Golden	Confectionery, non- alcoholic beverages and syrups made with synthetic flavours
Ultramarine (U.S. brand)	Azure blue	Mineral colouring matter	3Na2Al2Si2O6Na2SO3		Insoluble in water	Refined lump sugar
Carmine					Red	Confectionery, alcoholic beverages, and other food products
Saffron					Yellow	0.00
Indigo					Insoluble in water or oils	ŕ

¹ Nomenclature used in the United States. — ¹ Colour index (1956).

Table 1. - Colouring matters (concluded)
Organic, synthetic and inorganic

Substance Safflower Carotene Curcuma (obtained by deodorization) Oeno dye (obtained from grapes) Marigold pigment	Synonym	Chemical group and colour index number	Empirical formula	Chemical name	Colour in water or oil solutions Insoluble in water or oils Yellow Orange yellow Yellow Tellow Yellow Yellow	Colour in solutions Insoluble in Confectionery, alcowater or oils holic beverages, and other food products Yellow Margarine, butter Cherry red in an acid medium Yellow Margarine and food fats Margarine, butter Margarine, butter
briar) Trigonella powder (obtained from blue and green sweet clover)						Processed cheese, green cheese

Only three organic synthetic colouring matters are authorized: tartrazine (yellow), indigo-carmine (blue) and amaranth (red). The list of foods which may be coloured with synthetic substances is also severely restricted. Thus, confectionery products (candies, caramel, dragées, pastila, marmelad, zefir, the cream filling for pastry and cakes) may be coloured with any one of the three above-mentioned synthetic colours; nonalcoholic beverages, carbonated and noncarbonated waters and syrups may be coloured only with amaranth and tartrazine. Amaranth may also be used to tint alcoholic beverages (liqueurs, nalivki, anstoi the sugar is authorized by means of an inorganic colouring of refined lump sugar is authorized by means of an inorganic colouring substance — an ultramarine of a particular brand. The characteristics of the organic synthetic and inorganic colours as well as the foods to which they may be added are indicated in Table 1.

As the table indicates, the permitted colours are mostly of natural origin, obtained either from plant sources (leaves, stems, flowers and roots) or from animal sources, such as the insect cochineal (Coccus cacti). The colouring matters authorized for use in confectionery products, alcoholic beverages and dessert and beverage powders are: saffron, carmine, indigo, safflower, and oeno dye, obtained from pressed grape skins, as well as various natural fruit juices and syrups. The permitted colouring substances for butter and margarine are marigold pigment, carotene, and a dye extracted from sweetbriar (KMS). Margarine may, in addition, be coloured with annatto, which is also permitted for the colouring of cheese pastes. The colours used by the food industry must meet the standards set forth in the relevant GOSTS or TUS; they must be produced in specialized enterprises. Colour blends put out by dye factories may not be used for the colouring of foods.

The pastry and confectionery producers obtain the required colour mixtures by combining the permitted three colours, red, blue and yellow. Public health regulations prohibit the colouring of foods and beverages for the purpose of masking spoilage or with a fraudulent intent. In the U.S.S.R., naphthol yellow s and Sudan III were deleted from the permitted list of colours in 1959. Until that time, Sudan III had been used to tint

¹ A type of sweet made from fruits or berries.

² Candied fruit jelly.

^a A type of soufflé sweetmeat.

^{4, 5} Types of fruit brandy.
6 Jelly-like dessert.

the paraffin rind of cheese. Both of these colouring substances were classified as potentially dangerous by the International Symposium on Potential Cancer Hazards from Chemical Additives and Contaminants to Foodstuffs, held in Rome in 1956. Presumably, when naphthol yellow s is broken down in the body, the nitro group is converted into an amino group, causing the formation of beta-naphthylamine, which is known to have unquestionable carcinogenic properties. It had been thought earlier that this carcinogenic activity was cancelled by the sulpho group in naphthol yellow s and in other colouring matters which had been thought to be harmless owing to the presence of the sulpho group, such as light green SF, sea green B, and others, which are in fact carcinogenic (Hueper, 1957). The colour authorized in place of naphthol yellow s is tartrazine, which has exhibited no toxic or carcinogenic effects in long-term tests using laboratory animals.

Of course, none of the colouring matters used in foods has any nutritive value. It might therefore seem that their use is not warranted. However, food colours have a long history of use and of regulation. This is due partly to the fact that many food products lose their original colour in processing, sometimes even acquiring an unattractive pale, greyish tint, and partly to the fact that the public has long been accustomed to brightly coloured foods, particularly among confectionery products which imitate fresh fruits or vegetables with their original hues. Thus, a berry candy must not only have the shape of a berry but also its colour to make the association more complete. An attractive, nicely coloured product arouses a favourable emotional response, which plays an important physiological role. Consequently, although Soviet public health theory and practice have always been oriented toward a maximum limitation on the addition of any foreign substance to foods, it has not been possible to ignore altogether the consumer's preference.

From the health standpoint, natural colouring matters are the most acceptable. Industry is therefore making every effort to increase the production of natural colouring substances such as the oeno dye from grape skins, KMS from sweetbriar, marigold pigment, etc. In line with this, it is deemed advisable to gradually discontinue the unwarranted use of synthetic colouring substances in some foods and beverages. As an example, following the prohibition of Sudan III in the U.S.S.R., cheese has been produced with an uncoloured paraffin rind.

As mentioned above, the public health regulations of the country restrict to only a few the colours that may be used in foods, and limit

the foods that may be coloured. This unquestionably creates a wide margin of safety. Since 1938, the number of permitted synthetic organic food colours has been reduced from seven to three, which represents a positive contribution to public health.

Preservatives

At the present time, the preservatives used in the U.S.S.R. are limited to sulphur dioxide and sulphite preparations (potassium bisulphite, sodium bisulphite, sodium sulphite, sodium sulphite), benzoic acid, sodium benzoate, sorbic acid, boric acid, borax, hexamethylenetetramine, and hydrogen peroxide. Sulphur preparations and benzoic acid and its salts were permitted in the 1930s and are used as preservatives in many foods.

The foods in which the above-mentioned preservatives may be used appear in Table 2. The concentration levels are expressed in terms of either free or total sulphurous acid (the sulphur dioxide coefficient being equal to 0.78). These levels correspond to 20-40 mg/kg for free sulphurous acid, and to 100-3 000 mg/kg for total sulphurous acid, depending on whether the product must undergo further heat treatment or not. In foods not subjected to heat treatment, such as glazed fruit, jam, dried fruit consumed without prior cooking, fruit juices intended for the manufacture of nonalcoholic beverages, etc., the concentrations of sulphurous acid must not exceed 100 mg/kg; in cider and grape wine, 150-400 mg/kg. In foods subjected to heat treatment — such as berries used for further processing, fruit and berry purées — the permitted concentration of total sulphurous acid varies from 1 000 to 3 000 mg/kg.

Benzoic acid and its salts are permitted in concentrations of up to 1 000 mg/kg in the fruit and berry purées, juices, and pulp employed in confectionery production, in fruit and berry jams, fruit juices, in salmon caviar and in sprats; in marmelad, cooked pastila and pastila powder, baking mixes and food gelatin, concentrations of up to 700 mg/kg are authorized. Sodium benzoate at 1 000 mg/kg is used in the preparation of preserved fish products (anchovies and herring in spicy marinades) and of margarine.

The recent experiments conducted by A.D. Ignatev at the Institute of Nutrition of the Academy of Medical Sciences of the U.S.S.R. (1962-64) showed that laboratory animals (mice and rats) were definitely affected

by sulphurous and benzoic acid preservatives, even in the dosages permitted for use in foods (calculated per 1 kg of body weight). Sulphurous acid preparations inhibited weight gain, while benzoic acid preparations, in addition, sharply lowered the survival capacity of test animals subjected to brief periods of starvation. Administered together, sulphurous and benzoic acid salts produced in the animals a biologically adverse summated effect. It was also established that benzoic acid and sodium bisulphite have some carcinogenic properties.

It would appear, therefore, that the evidence from these experiments conflicts with the views and conclusions of the International Symposium on Potential Cancer Hazards from Chemical Additives and Contaminants to Foodstuffs, held in Rome in 1956, which classified preparations such as benzoates in Class I, i.e., among thoroughly investigated substances which satisfy the standards of safety. The same conference classified sulphurous acid preparations in Class II, among preservatives on which available information was still insufficient. Thus, despite the fact that sulphurous acid and benzoic acid have been used as food preservatives for several decades, a restriction on their use is called for immediately, as well as their replacement to the maximum extent possible with other innocuous preservatives.

A preservative which has been fully investigated and which satisfies the prerequisite of safety is sorbic acid. This acid has been found to be safe in large quantities; it is an effective preservative and has a favourable biological effect, reinforcing the body's immunoreactivity and its detoxifying capacity (A.D. Ignatev, 1965). Sorbic acid is authorized by the Soviet Ministry of Health and is used in a number of foods as a preservative and to prevent moulding in fruit juices, bread and bakery products, confectionery (marmelad, jams, fruit preserves, pastry cream) and in soft caviar; it is used to retard the formation of mould on cheeses and is added to evaporated milk to prevent darkening, since sorbic acid has the capacity of completely inhibiting the growth of brown mould in evaporated milk. The permitted concentrations of sorbic acid are set out in Table 2; they vary between 1000 and 2000 mg/kg of food product. Sorbic acid inhibits the dehydrogenase enzyme system of mould fungus. Given a weak dissociation constant (K = 1.73×10^{-5}), it is more effective at high pH levels than benzoic acid. The optimum pH level for its activity is around 4.5. At pH 5, sorbic acid is two to three times more effective than benzoic acid. The addition of acids and of common salt increases its fungistatic effect.

TABLE 2. - PRESERVATIVES

Substance	Chemical formula	Function	Permitted in:	Permit concentr in foo	ation
				mg/k	g
				Total	Free
Sulphurous acid and sulphur dioxide	H ₂ SO ₃	Preservative	Cider	150	20
surpliur dioxide			Wines	400	40
			Grape wine	200	-
			Jams	100	-
			Marmelad Pastila	} _	20
			Zefir, sprats	_	20
			Starch	100	-
			Candied fruits	100	30
			Fruit purées 1	1 000	-
			Fruit juices *	100	30
			Dry gelatin	1 000	-
			Dried fruit 3	1 000	
			Intermediate berry products:		
			sour cherries	3 000	_
			strawberries raspberries	2 000	_
			others	1 500	
Benzoic acid				mg/k	g
Benzoic acid	$C_7H_6O_2$	Preservative	Fruit preserves, mar- melad, pastila, con- fectionery mixes	70	0
			Sprats, salmon roe, fruit and berry juices, intermediate food products	1 000	0
Sodium benzoate	C ₇ H ₈ O ₂ Na	,,	Anchovy preserves	1 000	0
			Herring in jars	2 600	0
			Margarine, sprats	1 000	
Sodium metabisul-	Na ₂ S ₂ O ₅	,,	Dried potatoes	4 400	0
phite			Dried cabbage		
			Potato flakes	4 600	
Boric acid	H_3BO_3	**	Soft roe (sturgeon and salmon)	3 000	
			Confectionery mixes	1 500	0

TABLE 2. - PRESERVATIVES (concluded)

Substance	Chemical formula	Function	Permitted in:	Permitted concentration in foods	
Sodium tetraborate	Na ₃ B ₄ O ₇	Preservative	Canada	mg/kg	
Dodium tetraborate	14a ₃ B ₄ O ₇	Freservative	Sturgeon soft roe	6 000	
			Salmon soft roe	3 000	
Hydrogen peroxide	H ₂ O ₂	Preservative	Food gelatin	200	
		and bleach- ing agent	Bouillons for gelatin	5 200	
Sorbic acid	C ₆ H ₈ O ₂	To prevent moulding	Nonalcoholic bever ages	300-500	
			Fruit and berry juices	1 000	
			Soft roe	1 200	
			Bread and bakery products	1 200	
			Cheese	2 000	
		To prevent darkening	Evaporated milk	1 000	
		To prevent moulding	Semismoked sausage products	5 000	
Hexamethylenetetra- mine	C ₆ H ₁₂ N ₄ Preservative		Salmon soft roe	1 000 (mixed with borax)	
Antibiotic	Conditions for use		Permitted in:	Concentration in raw product	
				mg/kg	
Biomycin (chlortetracycline)	5 mg/ton of ice for fish conservation		Fish	Up to 0.25	
		f solution, in with nysta-	Meat	Up to 0.5	
Nystatin	200 mg/l in conjun chlortetracy		Raw meat	0	

For confectionery products. — For beverages. — Heat-processed. — Recalculated for SO₂. — In dry gelatin. — Authorized provisionally.

The use of boric acid, borax and hexamethylenetetramine is strictly limited in the U.S.S.R. These preparations are permitted, basically, only for the conservation of products not intended for mass consumption, such as various types of caviar. Thus, borax (sodium tetraborate) is used for the preservation of soft caviar of sturgeon and salmon species (3 000-6 000 mg/kg); hexamethylenetetramine for soft caviar of red salmon (1 000 mg/kg); boric acid, besides being used in amounts of 3 000 mg/kg for the preservation of soft caviar from sturgeon and salmon, is added to the mixes used in confectionery production in concentrations of 1 500 mg/kg.

The work done by various authors in recent years shows that preparations based on boric acid, borax and hexamethylenetetramine provoke certain undesirable reactions in the body and fail to satisfy the requirements for safety to health. In the U.S.S.R., they are used in very restricted quantities at present, and the need to replace them with other innocuous preservatives is receiving serious consideration.

Hydrogen peroxide is authorized as a preservative only for bouillon used in making gelatin, in quantities of up to 200 mg/kg of dry gelatin, and as a bleach for food gelatin at the same concentration. Sodium chloride is used widely in the preparation of salted and smoked meat, fish, and other products. Its utilization in the production of various foods is regulated by the appropriate GOSTS and TUS.

Strong interest has been manifested in many countries in recent years by antibiotics as a means of retarding spoilage in storage of such foods as fish, meat, poultry, fruits, etc. Investigations have shown conclusively that small doses of antibiotics used in the processing of these foods double their conservation time. This is an important factor particularly in the transport of meat over great distances and for the preservation of fish caught far out at sea.

It is well known that a prolonged intake of antibiotics may provoke physiological side effects, notably an increased susceptibility to various internal and environmental agents and alterations in the intestinal flora, which may bring about secondary bacterial or fungus infections, the appearance of candidomycoses and of resistant strains of bacteria (A. L. Libov, 1958, and others). The increasing caution manifested toward antibiotics in food production is thus entirely justified. To be authorized for use in the production of foods, antibiotics should meet certain conditions: they should be free from toxicity and should not affect the quality of food; they should have a wide spectrum of antibacterial activity and should be

readily inactivated when the food is heat-processed or stored. When foods are consumed, there should not be the slightest trace of active antibiotic present, lest it provoke the appearance of resistant strains of pathogenic bacteria. Furthermore, the prolonged ingestion of foods containing active antibiotics may cause undesirable changes in the normal intestinal flora. Only a few of the available antibiotics were found to satisfy the above requirements. Specifically, the treatment of meat and fish products with antibiotics under experimental conditions has shown that only chlortetracycline and oxytetracycline (Terramycin) are able to inhibit the growth of bacteria in these products.

Chlortetracycline (biomycin — $C_{22} H_{23} O_8 N_2 C1$) has a broad antibacterial spectrum but has no inhibiting effect on the development of moulds and yeasts. When heated, it turns into an innocuous isomer, isochlortetracycline, which is a bacteriostatic substance. Chlortetracycline is almost completely inactivated by common cooking methods.

The use of antibiotics should be accompanied by chilling, as this makes it possible to reduce the amount of antibiotics required, which is beneficial from a health point of view. Special research carried out in the U.S.S.R. in this field (Y. I. Rubinstein et al., 1960) showed that the freshness of fish is prolonged merely by the use of ice containing no more than 5 g of biomycin per ton of ice, making the submersion of fish in a biomycin bath unnecessary. At present, pending the elaboration of methods more acceptable from the health standpoint, the use of biomycin-treated ice is permitted as an interim measure in distant water trawl fisheries in a specified area and for the conservation of cod species only. Biomycin residues in raw fish tissue must not exceed 0.25 mg/kg. This guarantees the absence of biomycin in cooked fish and in fish broth. The organoleptic qualities of boiled and fried fish remain quite satisfactory.

There is considerable scientific evidence of the effectiveness of chlor-tetracycline also against the bacterial decay of beef in storage (V. I. Kurbo, 1958; V. P. Dyklop, 1959); however, the antiseptic action of chlor-tetracycline was reinforced when it was used in conjunction with another antibiotic, nystatin, which retards the development of mould and yeasts on meats. When both antibiotics are used, meat may be kept for up to seven or ten days. Toxicological analysis (Y. I. Rubinstein et al., 1963) showed such meat to be safe. On the basis of this evidence, the Ministry of Health at present provisionally allows meat carcasses to be sprayed with a solution containing 100 mg of chlortetracycline and 200 mg of nystatin per litre. Antibiotics may be used for meat conservation

only in combination with refrigeration, and exclusively for carcasses which are to be transported over long distances in refrigerated cars. No residue of chlortetracycline or nystatin should be present in meat following cooking (boiling, frying) or in meat bouillon. In an average assay of raw meat ready for marketing, the residue of chlortetracycline must not exceed 0.5 mg/kg of meat. No residues of nystatin in raw meat are tolerated. The organoleptic qualities of meat dishes (after boiling, frying, roasting) and of broths made from meat treated with antibiotics are quite satisfactory.

In the U.S.S.R., chlortetracycline may not be used for the conservation of milk or milk products, fruits, vegetables and berries. A limited number of fruit and vegetable products may be preserved exclusively by a brand of nisin made in the United Kingdom. Since nisin is not used in human therapeutics, the risk of its provoking the appearance of bacterial strains resistant to medical antibiotic treatment does not arise.

Antioxidants

Prevention of the spoilage of fat is one of the problems with which the food industry is most preoccupied at the present time. physiological value of fat depends not only on its palatability but also on its freshness, yet fats are readily subject to oxidation (deterioration) particularly under incorrect storage conditions. In recent years, the use of antioxidants to prevent the deterioration of fats through oxidation has become widespread. In the U.S.S.R., butylated hydroxyanisole and butylated hydroxytoluene are permitted for this purpose. The hygienic and toxicological investigations of these substances (I. A. Karplyuk, 1959, 1960, 1964) showed that the organoleptic qualities of foods prepared with pork fat containing maximum concentrations of these antioxidants were not different from those of control samples. Butylated hydroxyanisole and butylated hydroxytoluene at the recommended levels do not have a toxic effect, and there are no objections based on health considerations to concentrations of 100-200 mg/kg being used to retard the oxidation process in food fats. Similar data were obtained also in respect of dodecyl gallate. In the light of these findings, the Medical-Epidemiological Service of the Ministry of Health permits the addition of butylated hydroxyanisole and butylated hydroxytoluene to fats in amounts of 100 mg/kg of product; and to melted animal fats and salted lard, in

amounts up to 200 mg/kg. These antioxidants are also permitted (100 mg/kg) for the stabilization of vitamin A used in food concentrates. For the preservation of fats in food concentrates, dodecyl gallate is authorized at a level of 100 mg/kg of fat.

Ascorbic acid is also a good antioxidant. It is permitted for use in margarine at levels that are not limited. The list of permitted antioxidants and of the foodstuffs to which they may be added is shown in Table 3.

TABLE 3. - ANTIOXIDIZING SUBSTANCES OR ANTIOXIDANTS

Substance	Chemical formula	Function	Permitted in:	Permitted concentration in foods
Ascorbic acid	$C_6H_8O_8$	Retards oxi- dation of fats		mg/kg No limitation
Butylated hydroxy-	$C_{11}H_{16}O_{2}$	99	Fats	100
anisole			Salted lard	200
			Melted animal fats	200
Butylated hydroxy-	C ₁₅ H ₂₄ O	27	Fats	100
toluene	10 01		Salted lard	200
			Melted animal fats	200
Dodecyl gallate	C ₁₉ H ₃₀ O ₅	99	Fats used in food concentrates	100

Acids and bases

Organic and inorganic acids are used in various branches of the food industry for the purpose of giving certain foods an acid taste. In the U.S.S.R., the following food acids are permitted: adipic, tartaric, citric, lactic, trihydroxyglutaric, carbonic, acetic, orthophosphoric and malic. The addition of acids to foods is regulated. The authorized amounts are stated in the Gosts and Tus. Orthophosphoric acid, in accordance with the standards approved by the Ministry of Health of the U.S.S.R., may be used to impart an acid taste to confectionery products and to beverages in concentrations not exceeding 600 mg/kg of finished product. Malic acid is also permitted in confectionery in quantities of up to 1 200 mg/kg. The list of food acids is set out in Table 4.

			IAI	DLE 7 - F
Substance	Chemical formula	Function	Permitted in:	Permitte concentration food
Adipic acid	C ₆ H ₁₀ O ₄ CH ₂ CH ₂ -COOH	Food acid	Marmelad	mg/kg
Tartaric acid	CH ₂ -COOH C ₄ H ₆ O ₆ COOH CHOH CHOH COOH	29	Pastila Fruit purées Jams Stewed fruits	
Citric acid	C ₆ H ₈ O ₇ CH ₂ COOH CHOH CH ₃ COOH	99	Bread kvass, pastila, jams, stewed fruits, liqueurs Fish (some preserved fish) Nonalcoholic beverages	0.8 kg p 1 000 ca
Lactic acid	C ₃ H ₆ O ₃ CH ₃ CHOH-COOH	99	Bread kvass, butter made from fermented cream, nonalcoholic beverages, beer of the letnee type	
Trioxiglutaric acid	C₅H₅O ₇ OH-CH-COOH OH-CH OH-CH-COOH	>>	Bread kvass, butter made from fermented cream, nonalcoholic beverages, beer of the letnee type	-
Acetic acid	C₂H₄O₂ CH₃COOH	79	Marinades of vegetables Vegetables in vinaigrette sauce, and others	600-1 80 500
Orthophosphoric acid	H ₃ PO ₄	>>	Cooling beverages, con- fectionery products	600
Malic acid	C4H ₆ O ₄ CHOH-COOH	>>	Marmelad, confectionery products	1 200
Carbon dioxide	ĊH₃-COOH CO₃	>>	For beverages and car- bonated soda, and selt- zer water	_
Sodium bicarbonate	NaHCO ₃	Deacidifying agent stabilizer of suspensions, dough acrator	Evaporated milk, cocoa powder, pastry	300/kg o mass
Sodium carbonate	Na ₃ CO ₃	Imparts min-	Effervescent beverage powders, seltzer water	
Ammonium carbonate	(NH ₃) ₂ CO ₃	Emulsifier, aerator	Cocoa powder, pastry	

	Purity	requirements		
Arsenic	Lead	Heavy metal salts	Ferricyanic acid	Others
Jp to .00014%	Not allowed	Up to 0.005%		Free HCl up to 0.02% Free H ₂ SO ₄ up to 0.05%
Jp to .00014%	39	Not allowed	Not allowed	Free H ₂ SO ₄ up to 0.05%
				Alkaloids, ions of barium and of oxalic acid not allowed
t allowed	Copper not allowed	Copper not allowed	99	Hydrocyanic and free H ₂ SO not allowed
79	Not allowed	_	_	Acetone, ethyl acetate and fre mineral acids not allowed
		-		
39	"	Copper not allowed	_	H ₂ SO ₄ and its salts HCl and its salts not allowe Formic acid up to 0.5%
**	97	_	_	_
.00014%	***	_		H ₂ SO ₄ up to 0.05%
-	_	_	_	H ₂ S, CO, HCl H ₂ SO ₃ , HNO ₂ , NH ₃ and monoethanclamine not allowe

The above-mentioned acids are manufactured specifically for the food industry and must satisfy the health standards of the appropriate Gosts and TUs. The levels of harmful impurities in food acids are controlled either by the Gost applicable to a given acid or by special circulars issued by the Ministry of Health. As indicated in Table 4, there are regulations concerning the levels of arsenic, lead, and other salts of heavy metals, of free mineral acids (sulphuric acid), of some organic acids (oxalic, formic), as well as of other impurities in food acids. The analytical methods for food acids are set out in the appropriate Gosts.

Food acids are quite widely used in the production of confectionery products, beverages, and in the manufacture of food concentrates, kissel powders, jams, stewed fruits and some sauces. To give caramel and other sweets a pleasant acid taste, the confectionery industry uses crystalline water-soluble acids with a reduced sugar-inverting capacity and resistant to temperatures of up to 120°C. Tartaric and citric acids meet these requirements and are the acids most frequently utilized.

Although adipic acid, too, has low inversion capacity, it does not dissolve well in water at relatively low temperatures (30-40°C) and has a less pronounced acid taste than citric acid; it is used to a relatively small extent by the food industry. Lactic acid, when added to caramel mixture in liquid form (50-60 percent concentrations), liquefies the mixture and makes it less stable. Furthermore, it is subject to partial decomposition at high temperatures and is therefore unsuitable for acidifying caramel. Basically, lactic acid is used in butter made from fermented cream, and in some beverages: bread kvass,7 beer of the letnee type, etc. Trihydroxyglutaric acid does not dissolve well in caramel mass and disperses unevenly, which limits its utilization. This acid is used in the filling of caramel candies. Malic acid is somewhat less tart than citric or tartaric acid, and is therefore used in amounts 20-30 percent higher than for these acids.

In nonalcoholic beverages, the desired acid flavour of fruits and berries is obtained most commonly by the addition of tartaric, citric and lactic acids. Acetic acid is used for the pickling of various foods (vegetable or fish), in mixed salads and in other culinary preparations. To give effervescent beverages their pleasant tingling quality and effervescence, diluted carbonic acid is employed.

Bases are used by the food industry in the preparation of effervescent

⁷ A beer of slight alcoholic content, usually made from mixed cereals.

beverage powders, in bakery products as dough risers (baking powders), and to lower the acidity of evaporated milk (see Table 4). The permitted bases are sodium carbonate, potassium carbonate and sodium bicarbonate. There are no objections on health grounds to the use of these substances, and in most cases their level in foods is not controlled.

Flavouring agents and taste enhancers

In order to impart a particular flavour to some foods, industry resorts to food flavours. Food flavours are complex compounds which sometimes include 10 or 15 different ingredients. Most of these are synthetic aromatic substances, but natural essential oils, fruit juices or extracts are sometimes added to enhance the flavouring capacity of the food flavours. Flavours are used in the preparation of confectionery products, of alcoholic and nonalcoholic beverages, syrups, dessert powders and ice cream. Some synthetic aromatic substances such as vanillin and diacetyl are utilized in foods directly; thus, vanillin is used in some dairy products and in the decoration of bakery products; diacetyl is added to margarine to give it a pleasing milky odour.

With advances in chemistry, the number of synthetic aromatic substances is growing rapidly. Many have a delicate scent, imitating closely the aroma of essential oils; chemically, their composition is similar to that of natural substances extracted from plant material. Other synthesized compounds have their own distinctive scent, and structurally they do not resemble the components of natural essential oils. Although the synthetic aromatic substances are generally present in food flavours in relatively small amounts, it must nevertheless be borne in mind that not all of them, by far, have been investigated in respect of their physiological effects, and even less is known about their components, which may exert the cumulative effect of which mention has been made previously. The reason for this lies in the fact that, in most countries, the firms which manufacture food flavours patent their compositions, making scientific investigation of the ingredients more difficult.

The research work done on synthetic aromatic substances and natural essential oils and compounds extracted from plant material has shown that some substances have a toxic effect on laboratory animals. Thus, the experiments with essential oils performed as long ago as 1922 in the U.S.S.R. showed that anise and parsley oils have toxic properties which inhibit respiratory and cardiac function.

TABLE 5. - SYNTHETIC FLAVOURING SUBSTANCES USED AS INGREDIENTS OF FLAVOURS FOR FOODS AND BEVERAGES

	Maximum permitted concentration of food flavour in:		
Substance	Confectionery products	Nonalcoholic beverages	
	Grammes pe	r kilogramme	
Pineapple aldehyde	0.95	Not used	
Aldehyde C ₁₆	0.50	0.40	
Amyl acetate	535.55	70.57	
Amyl butyrate	75.00	Not used	
Amyl valerate	50.00	99	
Anisyl acetate	Not used	3.52	
Benzaldehyde	72.00	2.50	
Benzyl acetate	12.25	Not used	
Benzyl alcohol	12.25	39	
Butyl propionate	1.22	23	
Vanillin	72.00	4.00	
Heliotropin	20.00	Not used	
Diisoamyl ether	7.50	99	
Eugenol	Not used	0.35	
Ionone	1.00	Not used	
Cinnamaldehyde	25.00	"	
Coumarin	30.00	8.00	
Methyl anthranilate	0.68	Not used	
Aubepine	1.00	"	
Undecalactone	20.50	**	
Phenylacetaldehyde	0.50	99	
Phenylic alcohol	20.80	33	
Phenylethyl acetate	3.24	99	
Phenylethyl valerate	Not used	0.17	
Phenylacetic acid	0.64	Not used	
Citral	10.00	21	
Citronellol	0.43	91	
Ethylpelargonic ether or substitute	4.00	11	
Ethyl laurate	4.00	**	
Ethyl formate	24.00	"	
Ethyl caprylate	9.00	*1	
Ethyl salicylate	1.00	21	
Ethyl enanthate	3.2	91	
Ethylphenyl acetate	21.23	91	
Ethyl acetate	35.00	21.17	
Ethyl butyrate	60.00	30.00	
Ethyl valerate	2.50	3.52	
Ethyl cinnamate	4.0	Not used	

Note: The synthetic oils include among their components heliotropin, geranyl acetate, linalool, phenylethyl alcohol and geraniol.

Table 6. – Natural flavouring substances (essential oils, infusions, juices and extracts) used in the production of flavours for foods and non-alcoholic beverages

Substance	Flavour
ssential oils	Anise
	Orange
	Bergamot
	Geranium
	Lemon
	Tangerine
	Muscatel sage
	Rose
	Peppermint
	Petitgrain (Citrus bigaradia)
atural infusions	Cloves
	Cinnamon
	Orris root
	Black currant buds
	Nutmeg
	Orange oil
	Lemon oil
iices	Raspberry
	Sour cherry
xtracts	Bilberry
	Other fruits and berries

Oil of cloves proved to be an irritant of the renal parenchyma of dogs used in the experiment. A number of authors showed that some flavouring substances used in the food industry, such as citral and ionone, manifest biological activity even in very low concentrations. This is an indication that some synthetic aromatic substances may perhaps affect health, and that they may have the capacity of affecting metabolic processes.

The physiological effects of several synthetic flavouring substances were also investigated (Y. I. Shillinger, 1950). The substances studied were 12 of the compounds most frequently employed in the manufacture of food flavours: amyl acetate, n-butyl acetate, ethyl acetate, ethyl salicylate, ethyl formate, dodecyl aldehyde, heliotropin, vanillin, citral, ionone, undecalactone, and musk ambrette. Citral and ethyl formate, adminis-

tered over a four-month period to test animals, in concentrations of 2.9 mg/kg and 6.9 mg/kg respectively, provoked definite reactions: loss of body weight as compared to the controls and, in addition, some disturbance in the pigmentation and metabolic functions of the liver. In view of the toxicity of some synthetic aromatic substances and natural essential oils, and considering the wide use made of these substances by industry, it appears important to promote toxicological investigations of individual synthetic compounds and, more especially, of those complex combinations in which they are frequently utilized in food flavour production.

In the interests of public health, it is indispensable to restrict the use of synthetic aromatic substances in favour of an expanded production and utilization of natural juices, extracts and essential oils. The use of synthetic substances should be limited particularly in the foods and nonalcoholic beverages intended for children and for the ill, since these groups are less resistant to toxic influences than others. The pros and cons regarding the flavouring of foods and beverages and the composition of food flavours have been under consideration by the public health authorities on repeated occasions. As long ago as 1928, the People's Commissariat for Public Health of the R.S.F.S.R. prohibited the use of nitrobenzene, methyl salicylate, methyl beta-naphthyl ether (yara-yara), ethyl beta-naphthyl ether (nerolin), and the ethers of nitrous and nitric acids in the manufacture of food flavours. At present, the flavouring of foods is regulated by the Sanitary regulations for the flavouring of foods by synthetic aromatic substances and aromatic extracts, approved by the Soviet Ministry of Health in 1955. The sanitary regulations list the plant extracts which may be used for flavouring foods (52 items) and nonalcoholic beverages by the Main Medical-Epidemiological Division of the Ministry of Health of the U.S.S.R. The synthetic and natural aromatic substances appear in Tables 5 and 6. As may be seen from these tables, the flavours for nonalcoholic beverages contain only a few synthetic aromatic substances and in lower concentrations than in the food flavours used for confectionery products or alcoholic beverages. The flavours used in foods include 39 synthetic flavouring substances, those used in nonalcoholic beverages and syrups only 11. Table 6 lists the essential oils, infusions, juices and extracts most frequently used in food flavours.

The sanitary regulations also specify the foods in which flavours may be used or to which synthetic aromatic substances may be added directly. Thus, food flavours are authorized in confectionery products and alcoholic beverages, in nonalcoholic beverages and syrups, as well as in ice cream

TABLE 7. - SYNTHETIC FLAVOURING SUBSTANCES, FOOD FLAVOURS, ARTIFICIAL SWEETENERS AND TASTE ENHANCERS USED IN FOODS

Substance	Chemical formula	Permitted in:	Permitted concentration in foods
Food flavours	1	Confectionery Ice cream Nonalcoholic beverages Syrups Dessert powders Alcoholic beverages	mg/kg 4 000 3 000 1 000 1 000 1 000 500
Vanillin	C ₃ H ₈ O ₃	Biscuits Leavened breads Melon, cherry and grape jams Chocolate butter Oriental sweetmeats, soybean cookies, various bakery products, jellies, fresh white cheeses, milk kissels, creams, puddings, alcoholic beverages Ice cream Nonalcoholic beverages Syrups	21 000 300 500 50 200
Diacetyl	C ₄ O ₂ H ₆ CH ₃ COCOCH ₃	Margarine Toffee Butter made from fermented cream	5 6
Saccharine Sorbitol	C ₇ H ₅ O ₃ N SO ₂ C ₆ H NH CO C ₆ O ₆ H ₁₄	Confectionery for diabetics	

A list of synthetic flavour components of food flavours is presented in Tables 5 and 6.

2 Calculated for flour.

and dessert powders. Vanillin may be used in leavened breads and in some products made with milk (fresh white cheese, kissels, custards, jellies, puddings, ice cream); further, it may be used to flavour confectionery products, alcoholic and nonalcoholic beverages. Diacetyl is per-

TABLE 8. - GELLING AGENTS, STABILIZERS AND EMULSIFIERS

Substance	Chemical formula	Function	Permitted in:	Permitted concentration in foods
Agar from marine red algae		Gelling agent	Pastila	mg/kg No limitation
			Ice cream	
Agaroid vegetable		Gelling agent, stabilizer	Marmelad Pastila Ice cream	:
Sodium alginate		igent, stabilizer	Ice cream	, ,
Methyl cellulose		Stabilizer "		p p
Calcium lactate	C ₁₀ H ₁₀ O ₆ Ca		Potato flakes	1 500 in purée (75% moisture), mixed with CaCl ₂ and Na ₂ H ₂ P ₂ O,
Oleic acid	C ₁₈ H ₃₄ O ₃	Emulsifier in products in Bakery the form of a finely dispersed tionery water emulsion	Bakery and confec- tionery	
Pectin		Gelling agent	Marmelad	1
Vegetable gum		6 6	Filling for candies	1
Dibasic sodium pyrophos-	Na ₂ H ₃ P ₃ O ₇	Stabilizer, consistency improver		1500 in purée (75% (moisture), together with CaCl ₁ 3 000 - 4 000 in raw product
Potassium carbonate	K ₃ CO ₃	Emulsifier	Cocoa powder	
Magnesium carbonate	MgCO,	*	Chocolate, from low grades of cocoa beans	1 200
Calcium chloride	CaCI	Stabilizer	Potato flakes	1 500 in puree (75% moisture), together with Na ₃ H ₂ P ₃ O ₇ or calcium lactate
Emulsifier T-F (r	Blend of T-2 and T-1 Emulsifier (mixture of mono- and agent diglycerides of fatty acids)	Emulsifier agent	and improving Margarine and bread	1 800
Emulsifier r-2 (brand for Product margarine) fication acids C	0 1	Product of the esteri- Plasticizer and antispatter- fication of saturated fatty ing agent, bread improver acids C-16-C-18		1 800

mitted for use in margarine. Beverages and dessert powders to which flavours are added may not be called "fruit" desserts or beverages; the label must indicate that they were prepared with the addition of food flavours.

Table 7 lists the foods to which flavours may be added and indicates the permitted amounts of the synthetic and natural flavouring agents in mg/kg of product.

The flavouring of natural foods (coffee, cocoa, spices, etc.) for the purpose of enhancing their characteristic natural aroma is prohibited, as is also the flavouring of a food for the purpose of disguising spoilage or with fraudulent intent. Food flavours may be manufactured only by special establishments which must comply with the health regulations prescribed for establishments manufacturing products for use in foods. The food flavours and synthetic flavouring substances used by the food industry must conform to the standards prescribed in the corresponding GOSTS or TUS.

In many foods, natural spices are used in the course of production as taste enhancers: cinnamon, cloves, cardamom, anise, pepper, ginger, etc. Their use in foods is governed by recipes, and they are not subject to sanitary limitations. With taste-enhancing substances may be grouped the artificial sweeteners saccharine and sorbitol. Both of these substances are authorized exclusively for the sweetening of dietetic foods intended for diabetics. The labels on food products and beverages sweetened with these substances must carry an indication that they were prepared with saccharine and sorbitol. Inasmuch as saccharine is known to have adverse effects, work is being done at present to find an innocuous substance with sufficient sweetening power to replace it, and the exclusion of saccharine from the permitted list of flavouring substances is under serious consideration.

Gelling agents, stabilizers and emulsifiers

In the course of production of some foods, gelling and stabilizing agents (see Table 8) are added for technological reasons. These substances are obtained primarily from vegetable materials and from animal sources. For the purpose of obtaining a stable jelly for marmelad, pastila for the filling of candies, the following substances are used: pectin, sodium alginate (processed from the giant Pacific alga, *Macrocystis purifera*), vegetable agaroid, agar from marine red algae, vegetable gums. The Soviet Ministry of Health imposes no restrictions on the use of these

substances in foods; the amounts added to foods are determined by the corresponding recipes, GOSTS and TUS.

In foods such as ice cream, the characteristic consistency is obtained and maintained by the addition of stabilizing agents. Stabilizers contribute to giving ice cream its creamy texture, they retard melting and increase the viscosity of the mixture. In ice cream production, the following stabilizing substances are permitted: agar, vegetable agaroid, sodium alginate, methylcellulose and sodium caseinate. To stabilize potato flakes, calcium lactate and calcium chloride salts are mixed with disodium pyrophosphate. The levels of these chemicals are determined on the basis of 1 500 mg of each ingredient per kg of potato purée with a 75 percent moisture content obtained from the potato flakes. Disodium pyrophosphate in amounts of 3 000-4 000 mg/kg of raw product is also used in sausage products to improve their texture. Phosphates make sausage products juicier and more tender.

Emulsifiers are used primarily in the production of margarine and bread and bakery products. Two synthetic emulsifiers are permitted. Emulsifier T-2 brand, used in margarine, is obtained by the esterification of C₁₆ to C₁₈ saturated fatty acids and is utilized by industry as a plasticizer and antispattering agent. Emulsifier T-F is a blend of T-2 and T-1; the latter is a combination of mono- and diglycerides of fatty acids. The concentration of emulsifiers in breads and margarine must not exceed 1 800 mg/kg. In bread, bakery products and confectionery, emulsifying action is also obtained by a finely dispersed water emulsion of oleic acid. Inorganic salts such as potassium carbonate and magnesium carbonate are also used as emulsifiers, the first in preparing cocoa powder, the second in the production of chocolate from low-grade cocoa beans. The magnesium carbonate level must remain under 1 200 mg/kg. Some natural substances, such as phosphatides, hydrophilic lipids, etc., are also permitted for use in foods.

As the above enumeration indicates, this group of additives consists mainly of substances obtained from plant material and of the salts of organic acids and phosphates, which in the quantities authorized are relatively safe for human consumption.

Improving and polishing agents

This group consists of additives used by the food industry for various technological purposes. It includes vegetable substances (lecithin, phosphatides, soaproot extract), synthetic inorganic substances (nitrates,

nitrites, potassium bromate), and organic synthetic compounds (sodium citrate, sodium glutamate, etc.) as well as preparations obtained from fungal and bacterial enzymes. These additives are listed in Table 9.

Most significant from the point of view of health are the nitrites and nitrates (sodium nitrite and sodium and potassium nitrate), which are added to sausage products such as frankfurters, smoked pork products, some fancy canned meats, and to the pickling solutions used for curing meats, in order to maintain the "natural" reddish pink colouring of these foods. In addition, sodium nitrite and sodium nitrate are used in brynza 8 and rennet cheeses to prevent premature gas formation. Nitrates also have some preservative properties. It is a well-known fact that, as a result of the activity of denitrifying bacteria, the nitrates in meat are gradually metabolized into nitrites.

The work of a number of Soviet authors (F. N. Subbotin, S. P. Myasnikov, V. I. Popov) published in recent years (1958-65) demonstrates the undesirable effects of nitrates particularly on young children. Experimental data on laboratory animals also corroborate the harmful effects of nitrates. A study of the effects of nitrates on one to one and a halfmonth-old puppies and on adult dogs indicated that a relationship exists between the nitrate dosage and the appearance of methemoglobinemia in the puppies (F. N. Subbotin, 1961, 1962a). Nitrates in amounts of 5-25 mg/kg of body weight provoked the formation of up to 5 percent methemoglobin in the animals. The percentage of methemoglobin in the blood rose as the dose of nitrates was increased. The puppies in whom methemoglobin reached 45-75 percent did not survive. The administration of nitrates to mature dogs also provoked the appearance of methemoglobin, but its level in the blood, generally speaking, was not high (less than 10 percent). Doses of nitrates of 200-350 mg/kg of body weight, which caused the death of some of the puppies, induced only 7 percent methemoglobin in adult dogs. By feeding two-month-old puppies 150-300 g of cooked sausage daily, F. N. Subbotin (1962b) observed blood methemoglobin levels of 2 to 10 percent. By feeding sausage with varying concentrations of nitrates to dogs aged seven months to two years, it was shown that the blood methemoglobin level rose as the dose of nitrates per kg of body weight was increased. Thus, 0.5 mg of nitrates per kg of body weight produced 8 percent (average) methemoglobin; 1 mg/kg 11.5 percent; 2 mg/kg 14.9 percent. The rise of methemoglobin

^{*} Salted cheese made from sheep's milk.

Substance	Chemical formula	Function	Permitted in:	Permitted concentration in foods
Sodium nitrite	Na No.	Fixes colour of meat prod- Ham, cooked and smokucts and prevents blowing ed sausages, frankfurtup in cheeses ers; certain canned meats, salted meat	Ham, cooked and smoked sausages, frankfurters; certain canned meats, salted meat	mg/kg 200
			Brynza, rennet cheeses	300
Potassium nitrate	KNO3	Fixes colour of meat prod- Frankfurters ucts; antimicrobial preser- Roe, canned tongue vative	Frankfurters Roe, canned tongue	1 000
Sodium nitrate	NaNO ₃	Fixes colour, antimicrobial Sausage products, preservative	Sausage products, ham Canned products	300
		Prevents blowing up in cheeses	in Brynza, other cheeses	300
Potassium bromate	KBr O ₃	Bread improver	Bread flour	40
Sodium potassium tartrate	C,H,O,NaK	Consistency improver	Processed cheeses	2 500
Sodium glutamate	C ₅ H ₅ O ₄ Na COOHCH ₂ CH ₂ CHNH ₂ COON _a - H ₂ O	Taste enhancer	Canned foods, food con- centrates	No limitation
Carbonyl diamide	N,H,CO NH,CONH,	Dough improver	Leavened dough	1 000-2 000 in flour in conjunction with orthophosphoric acid
Potassium ferrocyanide	K, [Fe(CN) ₆] ₃ H ₈ O	To remove excess iron (if more than 8 mg/1)	iron Wine	No cyanides in finished wine
Lecithin	l	Bread improver and thera-Breads peutic agent in atheroscle-Cocoa powder rosis	Breads Cocoa powder	3 000
Sodium citrate	C,H,O,Na	Cheese emulsifier, acidifying Processed cheese, evapoagent	Processed cheese, evaporated milk, marmelad	000 9
Sodium lactate	C ₃ H ₅ O ₂ Na CH ₃ CHOHCOONa	sizer	Ice cream, marmelad	000 9
Phosphates: mixture of so-Na ₄ P ₂ O ₇ .IOH ₂ O - 55% dium pyrophosphate and NaHPO ₄ FH ₃ O - 45% monosodium phosphate	Na ₄ P ₂ O ₇ .IOH ₂ O - 55% NaHPO ₄ FH ₃ O - 45%	Improver	Jams Sausage products Canned stuffing	4 000 (mixed) 1 500 (mixed)
Ficin (from fig juice)	1	Hastens maturing	Meats	

Substance	Chemical formula	Function	Permitted in:	Permitted concentration in foods
FUNGAL ENZYME PREPARA-				m8/kg
Enzyme from: Aspergillus awamori 673		Bread improver	Breads	Up to 500 (per kg of flour)
Trichotecium roseum		Quality improver	Beer	, 1
Aspergillus terricola 3374		Hastens curing	Salt herring	1 000
Aspergillus oryzae KC		86	ф.	1 000
Aspergillus oryzae 3-9-15		Bread improver	Breads	30
Aspergillus flavus 716		Beer improver	Веег	100 mg/1 of barley mash
Phosphatides		Quality improver	Candies	
Orthophosphoric acid (H ₃ PO ₄)		Dough improver	Wheat bread	500 (in conjunction with carbonyl diamide)
Monosodium phosphate	Na H ₂ PO ₄ .FH ₂ O	Consistency improver and Processed cheese emulsifier Cheeses, sausag cooking, pork furters	Processed cheese Cheeses, sausages for cooking, pork frank- furters	400 (in milk)
Disodium phosphate	Na ₂ HPO ₄	Consistency improver	Processed cheese Cheeses, sausages for cooking, first and second quality	400 (in milk)
		Anticrystallization agent	Sterilized evaporated milk	
Calcium chloride	CaCl ₂	Improver	Marmelad Cheeses Brynza Grating cheese	333 500 (in milk) 1 500 200 (in milk)
Magnesium chloride	1	Imparts taste to beverages Seltzer water Soda water	Seltzer water Soda water	
Soaproot saponin extract	MgCl ₂	Foaming agent	Caramel mass for halva	Caramel mass for halva 20 000 of extract or 300 of saponin

CONTINUE ACTIVITY (CONCINUED)

levels brought on varying degrees of hypoxia in the animals (S. P. Myasnikov, 1965). This author believes that the appearance of methemoglobin is due not only to the action on haemoglobin of the nitrites which are absorbed into the bloodstream but also to the presence of other substances in the sausage meat. The reciprocal interaction of the nitrites and nitrates with meat haemoglobin and methemoglobin provokes the formation of nitrose compounds in the meat. In the process, intermediate products are formed, such as hydroxylamine (up to 2.5 percent), a substance which also promotes methemoglobin formation.

In view of the evidence, and at the request of the Soviet Ministry of Health, the meat industry's technical research institutes are at present seeking a way to lower the nitrite and nitrate content of sausages and other products. Until substitutes can be found, the permitted nitrate and nitrite levels in sausage products has been lowered to 3-10 mg/kg.

The possible utilization of preparations of fungal and bacterial enzymes in various branches of the food industry is at present arousing considerable interest. The use of enzyme preparations allows increased production, speeding up of the technological processes (e.g., the curing of herring, etc.) and improving the characteristics of products (bread, juices, beer, etc.). Before being authorized for use, enzyme preparations undergo thorough study from the health standpoint, since among enzyme-producing fungi there are toxic varieties. On the basis of research evidence, the Soviet Ministry of Health authorized the baking industry to use enzymes from fungus Aspergillus oryzae G. K., strain 3-9-15, and from Aspergillus awamori, strain 673, in amounts of 30 and 500 mg respectively per kg of flour, as bread improvers. By hastening the hydrolysis and intensifying the fermentation of the dough, these enzymes markedly improve bread characteristics: the soft part is noticeably airier, the bread has a more appetizing taste and aroma, and the crust a more attractive colour. In beer brewing, cytolytic enzymes added to the malting barley help to break down the cell walls of the endosperm, thus hastening the hydrolysis of the material stored in the kernel and facilitating the access thereto of other enzymes. The addition of enzymes to the mash in brewing increases the output of beer, improves its characteristics and its keeping qualities in storage. On the basis of the evidence obtained from tests with a preparation from Trichotecium roseum (V. P. Bogoroditskaya, and N. E. Dobyuk, 1965), the Ministry of Health decided to authorize provisionally the use of this product in the brewing of beer.

An enzyme preparation from the fungus Aspergillus flavus P.K., strain 716, is also authorized as a beer improver. In addition, preparations from Aspergillus terricola P.K., strain 3374, and Aspergillus oryzae P.K., strain KC (see Table 9) are permitted to hasten the curing of salt herring.

To shorten the seasoning time of meat, ficin — an enzyme of vegetable origin obtained from the juice of figs — is permitted. This enzyme is used to treat meat cuts before cooking; it induces hydrolytic alterations in the meat protein, and produces tender, soft, and pleasant-tasting meat.

Potassium bromate, orthophosphoric acid in combination with carbonyl diamide urea, and lecithin are authorized as bread improvers. Lecithin is also added to bread therapeutically for people with atherosclerosis. Potassium bromate added to bread flour in small quantities makes the soft part of the bread spongier, softer and whiter. Carbamide and orthophosphoric acid added to the leavened dough help to produce good-quality bread from flour with poor baking properties.

In the production of processed cheese, emulsifying salts are used to make the paste more homogeneous and softer: sodium potassium tartrate, sodium citrate, monosodium phosphate, and others. In sausage products, phosphates are permitted as plasticizers and to improve the texture of the products: sodium pyrophosphate combined with monosodium phosphate, tripolyphosphate combined with monosodium orthophosphate, and also mono- and disodium phosphate. The latter is also permitted for use in cheeses.

In the production of ice cream and marmalade, sodium lactate may be added for the purpose of creating the consistency typical of these foods.

The Ministry of Health authorizes the use of soaproot extract as a foaming agent; this extract, which contains saponin, is permitted exclusively as an additive to the caramel mass in the making of halva. The quantity of saponin must not exceed 300 mg/kg of caramel mass.

To reinforce and "freshen" their natural taste and aroma, canned vegetables and meats may have sodium glutamate added as a flavour enhancer.

Magnesium chloride is used in the production of beverages such as seltzer and soda water, to give these products their characteristic tang.

The specifications in respect of additives whose concentrations in food are limited are set out in Table 9. As regards polishing agents, the Ministry of Health allows medicinal vaseline, fat-wax products, dextrin

TABLE 10. - POLISHING AGENTS

Substance	Function	Permitted in:	Permitted concen- tration in foods
			mg/kg
Medicinal vaseline	Polishing agent	Caramel	_
Fat-wax products	Surface glazing agent	Candies, dragées	
Dextrin (vegetable)	Polishing agent	Caramel	_
Paraffin, brand A	99	93	
Talc	Polishing agent 1	**	2 500
		Dragées	2 500

¹ Also prevents candies from adhering.

and paraffin to be used in the confectionery industry to make caramel candies and dragées glossy. It also permits the use of talc to prevent candies and dragées from adhering during polishing; the presence of talc in the finished product is limited to 2 500 mg/kg (see Table 10).

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